K110350

bio-medical research ltd.

Bio-Medical Research Ltd.

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AUG - 3 2011

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Contact Details

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Prepared:	July 25, 2011.

2. Device Name

Trade Name of Device:	Kneehab XP, Type 412/421
Common Name:	Transcutaneous Electrical Nerve Stimulator
	Powered Muscle Stimulator
Regulation Number:	21 CFR 882.5890
	21 CFR 890.5850
Regulation Description:	Transcutaneous electrical nerve stimulator for pain relief
	Powered muscle stimulator
Product Code:	IPF, GZJ, NYN
Device Class:	2

3. Identification of Equivalent Legally Marketed Device

510(k) Number:	K083105
Manufacturer:	Bio-Medical Research Ltd.
Trade Name:	Kneehab XP Conductive Garment, Type 411

510(k) Number:	K082011
Manufacturer:	Bio-Medical Research Ltd.
Trade Name:	MediStim XP, Type 281

510(k) Number:	K082011
Manufacturer:	Bio-Medical Research Ltd.
Trade Name:	MediTens XP, Type 458

510(k) Number:	K061516
Manufacturer:	Compex Technologies, Inc
Trade Name:	Staodyn Max Preset

510(k) Number:	K021100
Manufacturer:	Empi
Trade Name:	300 PV Complete Electrotherapy System

510(k) Number:	K971437
Manufacturer:	BioniCare Medical Technologies
Trade Name:	Bionicare® Stimulator System

4. Description of Device

The Kneehab XP, Type 412/421 is a portable, battery operated, combination device which can provide both neuromuscular electronic stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS). The device incorporates multipath®, a patented technology developed by neurotech® which enables the Kneehab XP Conductive Garment to deliver highly focused and accurate NMES muscle contractions. This device also provides a method of pain management and relief through the use of TENS technology.

The Kneehab XP pack consists of a rechargeable control unit, a left or right universally sized garment, a pack of custom adhesive electrodes, a battery charger and instructions for use. The garment is fastened around the thigh and above the kneecap and contains a connector socket into which the control unit is plugged. Power is derived from a 3.6V NiMH rechargeable battery pack that is pre-installed in the unit. A battery charger is included with

the device and the device cannot be used while being charged. The adhesive electrodes have an estimated usage capability of 20 sessions when used under the recommended conditions of use.

All internal connections of the unit are over molded to prevent moisture ingress. The user has no access to the wiring or connectors within the garment and is unable to alter the current path. There are nine treatment programs in total (six NMES and three TENS) with a duration of 20 minutes each. Program details are included in the instructions for use. For purposes of hygiene, the garment may be cleaned and instructions for device care are included in the user manual.

5. Statement of Intended Use and Indications for Use

Kneehab XP, Type 412/421 delivers stimulation based on the principles of NMES and TENS. NMES may be defined as the application of electrical stimulation of the peripheral nervous system to contract a muscle, either through the direct activation of the motor neurons in the mixed peripheral nerve, or indirectly through reflex recruitment. TENS can be defined as a pain therapy based on the application of electrical stimuli to the skin via stimulation of the nerve fibers.

In NMES mode (Programs 1-6), the Kneehab XP, Types 412/421, is indicated for use as follows:

1. Maintain or increase the range of motion.
2. Prevention or retardation of disuse atrophy
3. Re-educate muscles
4. Early post-surgical quadriceps strengthening and improved post surgical knee stability secondary to quadriceps strengthening
5. Relax muscle spasms
6. Increase blood circulation

Programs 1-6 use multipath technology.

Neuromuscular Electrical Stimulation (NMES) Programs on Kneehab XP:

Program Number	Duration (Minutes)	Frequency/ Rate (Hz)	Pulse Width (μsec)	Ramp Up Time (seconds)	Contraction Time (seconds)	Ramp Down Time (seconds)	Relaxation Time (seconds)	Additional Function	Indication No.
P1	20	50	300-400	1	5	0.5	10	Trigger	4
P2	20	50	300-400	1	10	0.5	10	Trigger	1, 2, 3, 5, 6
P3	20	50	300-400	1	10	0.5	20	Trigger	1, 2, 3, 5, 6
P4	20	50	300-400	1	10	0.5	30	Trigger	1, 2, 3, 5, 6
P5	20	35	300-400	1	5	0.5	5	Trigger	1, 2, 3, 5, 6
P6	20	70	300-400	1	10	0.5	50	Trigger	1, 2, 3, 5, 6

In TENS Mode (Programs 7 - 10), the Kneehab XP, Type 412/421 is indicated for use as follows:

7. Provide symptomatic relief and management of chronic, intractable pain
8. Provide an adjunctive treatment in the management of acute, post-surgical or post-traumatic pain
9. Provide symptomatic relief and management of intractable pain and relief of pain associated with arthritis
10. Provide an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee
11.

Transcutaneous Electrical Nerve Stimulation (TENS) Programs on Kneehab XP:

Program Number	Duration (Minutes)	Frequency/ Rate (Hz)	Pulse Width (μsec)	Ramp Up Time (seconds)	Contraction Time (seconds)	Ramp Down Time (seconds)	Relaxation Time (seconds)	Additional Function	Indication No.
P7	30	99	300	N/A	Continuous	N/A	N/A	No Trigger	7 -10
P8	30	4	300	N/A	Continuous	N/A	N/A	No Trigger	7, 8, 9
P9	30	125	175	N/A	Continuous	N/A	N/A	No Trigger	7, 8, 9

6. Summary of Technological Characteristics

There are no new technological characteristics that could affect safety or effectiveness of the Kneehab XP, Type 412/421 device. A summary of the technological characteristics of the new device in comparison to the predicate device has been included below:

General Comparison	Proposed Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Name of Device:	**Knechab XP**	**Knechab XP Conductive Garment**	**MediTens XP**	**MediStim XP**	**Staodyn Max**	**300 PV Complete Electrotherapy System**	**Bionicare® Stimulator System**
510k Number:	**K110350**	**K083105**	**K082011**	**K082011**	**K061516**	**K021100**	**K971437**
Intended Use	The Knechab XP is intended to provide transcutaneous Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS).	The Knechab XP is intended to provide transcutaneous Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS	The MediTens XP is intended to provide Transcutaneous Electrical Nerve Stimulation (TENS).	The Knechab XP is intended to provide transcutaneous Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS)	The Knechab XP is intended to provide transcutaneous Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS	The 300 PV is a multifunction electrotherapy device intended to provide Neuromuscular Electrical Stimulation (NMES), Transcutaneous Electrical Nerve Stimulation (TENS), Interferential Current Stimulation (IFS) and Functional Electrical Stimulation (FES).	The Bionicare is a battery operated TENS stimulator producing pulses at 100 Hz. Electrodes are applied to the knee and thigh.
Prescriptive Use	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Indications for Use	In NMES mode (Programs 1-6) the Knechab XP is intended to: Maintain or increase range of motion, Prevention or retardation of disuse atrophy, Re-educate muscles, Early post-surgical quadriceps strengthening and improved post surgical knee stability secondary to quadriceps strengthening, Relax muscle spasms & Increase local blood circulation In TENS Mode (Programs 7 - 9) the Knechab XP is intended to: Provide symptomatic relief and management of chronic, intractable pain, Provide an adjunctive treatment in the management of acute, post-surgical or post-traumatic pain, Provide	Muscle re-education of the quadriceps, Maintaining or increase range of motion of the knee joint, Prevention or retardation of disuse atrophy in the quadriceps, Early post-surgical quadriceps strengthening and improved post-surgical knee stability secondary to quadriceps strengthening & increasing local blood circulation.	The symptomatic relief and management of chronic intractable pain. It is also an adjunctive treatment in the management of post-surgical and post-traumatic pain. The device has no curative value and should only be used in conjunction with medical supervision.	Neuromuscular Electrical Stimulation (NMES) for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis and maintaining or increasing range of motion. Transcutaneous Electrical Nerve Stimulation (TENS) for an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.	The Staodyn® Max Preset Transcutaneous Electrical Nerve Stimulator Device is used for the symptomatic relief and management of chronic intractable pain and relief of pain associated with arthritis. It is also used as an adjunctive treatment in the management of post-surgical and post-traumatic pain	(TENS/NMES Indications for use) As a NMES device, the 300 PV is indicated for the following conditions: Re-educating muscles, Relaxation of muscle spasm, Increasing local blood circulation, Retarding or preventing disuse atrophy, Maintaining or increasing range of motion & Prevention of venous thrombosis of the calf muscles immediately after surgery As a TENS device, the 300 PV is indicated for the following conditions: Symptomatic relief and management of chronic, intractable pain and Adjunctive treatment for post-surgical and post-trauma acute pain	Provide an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee

General Comparison	Proposed Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Name of Device:	**Kneehab XP**	**Kneehab XP Conductive Garment**	**MediTens XP**	**MediStim XP**	**Staodyn Max**	**300 PV Complete Electrotherapy System**	**Bionicare® Stimulator System**
510k Number:	**K110350**	**K083105**	**K082011**	**K082011**	**K061516**	**K021100**	**K971437**
	symptomatic relief and management of intractable pain. Relief of pain associated with arthritis. Program 7 provides an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee.						
Energy Used or Delivered:	3.6V NiMH Rechargeable Battery Pack	Same as proposed device	9V Battery (type 6LR61)	9V Battery (type 6LR61)	3 x AAA Batteries	2 x AA	9V Battery (type 6LR61)
Unit:	Constructed from injection moulded thermosetting plastic (ABS-PA-757).	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not available	9V Battery (type 6LR61)
Garment:	Contains an EEPROM. Outer Fabric:100% Nylon, Inner Fabric: 70% Polychloroprene & 30% Polyurethane, Binding: 82% Nylon & 18% Elastane. Fastenings:100% Nylon	Same as proposed device	Not Applicable (N/A)	N/A	N/A	N/A	Garment wraps around knee and thigh, contains conductive surfaces onto which conductive gel is applied.
Electrode	Electrode A: 194 cm2, Electrode B: 74 cm2, Electrode C: 83 cm2 and Electrode D: 66 cm2	Same as proposed device	Industry standard electrodes 5 x 5cm & 7 cm round 5 cm x 9cm etc.	Industry standard electrodes 5 x 5cm & 7 cm round 5 cm x 9 cm etc.	Industry standard electrodes 5 x 5cm & 7 cm round 5 cm x 9 cm etc.	Industry standard electrodes 5 x 5cm & 7 cm round 5 cm x 9 cm etc.	2 of 12 x 9 cm approx
Lead Wires:	Over-moulded SATA connector, splitting to 5 leads / studs.	Same as proposed device	Set of two (dark blue and light blue), each lead wire has 2 wires and terminates with a 2mm moulded pin for connection to electrodes. Constructed of PVC insulated, containing 7-strand tinsel copper with interwoven Kevlar reinforcing fibers.	Set of two (dark blue and light blue), each lead wire has 2 wires and terminates with a 2mm moulded pin for connection to electrodes. Constructed of PVC insulated, containing 7-strand tinsel copper with interwoven Kevlar reinforcing fibers.	Set of two, each lead wire has 2 wires and terminates with a 2mm moulded pin for connection to electrodes.	Set of two, each lead wire has 2 wires and terminates with a 2mm moulded pin for connection to electrodes.	Set of two, each lead wire has 2 wires and terminates with a 2mm moulded pin for connection to electrodes.
Charger:	PC/ABS, complies with IEC 60950 and UL 1950	Same as proposed device	N/A	N/A	N/A	YES, charges batteries external to unit	N/A
Standards Met	IEC 60601-1 (1998) & A1:	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not Available	Not Available

General Comparison	Proposed Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Name of Device:	**Kneehab XP**	**Kneehab XP Conductive Garment**	**MediTens XP**	**MediStim XP**	**Staodyn Max**	**300 PV Complete Electrotherapy System**	**Bionicare® Stimulator System**
510k Number:	**K110350**	**K083105**	**K082011**	**K082011**	**K061516**	**K021100**	**K971437**
	1991, A2: 1995, IEC 60601-2-10 (1987) & A1: 2001, IEC 60601-1-2 (2001), ISO 14971:2007, ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2002 & A1:2006 21 CFR 898 21 CFR 801						
Biocompatibility	Electrodes - K000947	Same as proposed device	Electrodes - K970426, K874469 & K965194	Electrodes - K970426, K874469 & K965194	Not available	Not available	Not Available
Compatibility with the environment & other devices	Complies to IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not Available	Not Available
Sterility	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Electrical & Mechanical Safety	Complies to IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety & IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not available	Not available
Chemical Safety	MSDS Sheet (Electrode Gel)	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not available	Not available
Thermal Safety	Complies to IEC 60601-1 & IEC 60601-2-10	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not available	Not available
Radiation Safety	N/A	N/A	N/A	N/A	Not available	Not available	Not available

UNIT Comparison	Proposed Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Name of Device:	Kneehab XP	Kneehab XP Conductive Garment	MediTens XP	MediStim XP	Staodyn Max	300 PV Complete Electrotherapy System	
510k Number:	K110350	K083105	K082011	K082011	K061516	K021100	
Manufacturer	China Turnkey Solutions Logistics (Shenzhen) Co.,Futian Free Trade Zone, CHINA 518038	Same as proposed device	Same as proposed device	Same as proposed device	Compex Technologies	Empi 599 Cardigan Road St. Paul, Minnesota 55126-4099	BioniCare Medical Technologies, Inc., 47 R Loveton Circle Sparks, MD 21152
-Method of line Isolation	No line connection	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device
Patient Leakage Current	N/A	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	No line connection
No. of Output Modes	1	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Several. eg Hi Volt, FES.	1
Waveform/Shape	Pulsed, Symmetrical, Biphasic, Rectangular with interphase interval	Same as proposed device	Same as proposed device	Same as proposed device	Symmetrical Biphasic Square	Asymmetric and Symmetric square wave options, Hi Volt pulse option; exponential spikes.	Monophasic spike shaped pulse
No. of Output Channels	2	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	2
Synch/Alternating?	Synchronous (Multiplexed)	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Synchronous and alternating	Synchronous
-Method of channel Isolation	Transistor	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Transformer	unknown
Regulated Current or Regulated Voltage	Regulated Current	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Claimed to be regulated voltage
Software/Firmware/ Microprocessor Control?	Yes	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device
Automatic Overload Trip?	Yes, current limited, indefinite short circuit allowed	Same as proposed device	Same as proposed device	Same as proposed device	Unknown	Unknown	unknown
Automatic No-Load Trip?	Yes	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	unknown
Automatic Shut Off?	Yes	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Unknown
Patient Override Control?	Yes, pause button	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Yes, Pause, FES modes	Yes stop button ends treatment

UNIT Comparison	Proposed Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Name of Device:	Kneehab XP	Kneehab XP Conductive Garment	MediTens XP	MediStim XP	Staodyn Max	300 PV Complete Electrotherapy System	
510k Number:	K110350	K083105	K082011	K082011	K061516	K021100	
Timer range (mins)	20 mins – open	Same as proposed device	Open	30 minutes – open	120 mins	5 mins to open.	Open
Weight (unit)	116g (inc. batteries)	Same as proposed device	142g (inc. batteries)	142g (inc. batteries)	145g	226g	136g
Dimensions (W x H x D)	60x23x115mm	Same as proposed device	105x68x28mm	105x68x28mm	2.5" x 5.25"x 1.0"	1.26" x 3.3" x 4.5"	95x64x30mm
Frequency/ Phase Duration of program with highest output power.	Program 7 99Hz 300µS	Program 1 50Hz 400 µS	Program 3 99 Hz 150µS	Program 3 50Hz 400 µS	Program A 100Hz 350µS	Custom User 2 150Hz 400uS	100Hz 640uS
Baseline to Peak Current	80mA @500Ω 28mA @2kΩ 3.9mA @10kΩ	80mA @500Ω 28mA @2kΩ 3.9mA @10kΩ	75mA @500Ω +/- 10% 35mA @2kΩ 7mA@10kΩ	75mA @500Ω +/- 10% 35mA @2kΩ 7mA@10kΩ	60mA@500Ω	100mA @500Ω	24mA @ 500Ω
Baseline to Peak Output Voltage	40.0V @500Ω 55.6V @2kΩ 39.3V @10kΩ	40.0V at 500 Ω 55.6V@ 2k Ω 39.3V at 10k Ω	37V @500Ω 70V @2kΩ 70V@10kΩ	37V @500Ω 70V @2kΩ 70V@10kΩ	30V @500Ω	50V @500Ω	12V 500Ω
Maximum RMS Output Voltage (+/-10%) V_{rms}	9.3 V @ 500 Ω 17.1V @ 2kΩ 14.1V @10kΩ	9.15V@ 500Ω 10.74V @ 2kΩ 5.65V@10kΩ	6.4 V @500Ω 12.1V @2kΩ 7 V@10kΩ	7.5V@500Ω 14 @2kΩ 7 V @10kΩ	8.85V @500Ω	10.5V @500Ω	4.3V Estimated assuming a square pulse shape 0.64ms
Maximum RMS Output Current (+/-10%) I_{rms}	18.6 mA@500 Ω 8.6 mA@ 2kΩ 1420 µA@10kΩ	18.3mA@ 500Ω 5.37mA @ 2kΩ 565µA@10kΩ	12.8mA @500Ω 6.1mA @2kΩ 700µA@10kΩ	15mA @500Ω 7 mA @2kΩ 490µA@10kΩ	15.9mA @500Ω	21mA @500Ω (As stated in device IFU, however is inconsistent with other stated parameters)	8.6mA
Pulse Width	640 µs -sum of both phases 300us +40 us interphase interval	840µs (both phases max 400uS with interphase interval of 40uS)	300µS(sum of both phases; 150µS) (Prog 1)	800µS(sum of both phases; 400µS) (Prog	700µS - sum of both phases; 350µS (Prog A)	1200µS, sum of both 400µS phases and interphase interval	640 µS
Net Charge (µC per pulse)	0µC @ 500Ω	0µC @ 500Ω	0µC @ 500Ω	0µC @ 500Ω	0µC @ 500Ω	<20µA	Not available
Maximum Phase Charge @500Ω (+/-20%)	24 µC @ 500Ω	32.8µC	10.5µC @ 500Ω.	30 µC	21 µC @ 500Ω.	40 µC	21 µC @ 500Ω
Maximum Current Density @500Ω	=18.6 mA/83 cm^2 =0.22 mA/ cm^2	0.22 mA/cm2	Using 2" square electrode = 12.8 mA/25 cm^2 = 0.5 mA/ cm^2	Using 2" square electrode = 15 mA/25 cm^2 = 0.6 mA/ cm^2	Using 2" square electrode =15.9 mA/25 cm^2 = 0.64mA/ cm^2	Using 2" square electrode =21 mA/25 cm^2 = 0.84mA/ cm^2	Using 12 x 9 xm electrodes =8.6 mA/108 cm^2 =0.08 mA/ cm^2
Maximum Power Density @500Ω (using smallest electrode conductive surface area)	Program 7 2.1mW/cm^2 @ 500Ω	2.55 mW/cm2	3.3 mW/cm^2	4.5 mW/cm^2	2.9 mW/cm^2	8.8 mW/cm^2	0.34 mW/cm^2
Burst Mode (ie pulse trains)	YES, NMES on off cycle	Yes, NMES on off cycle	Yes, burst mode TENS	Yes, NMES on off cycle	Yes, burst mode TENS	Yes, NMES and TENS modes	Yes

7. Substantial Equivalence

Bio-Medical Research Ltd (BMR) has over 30 years experience in the research, design, manufacture and marketing of medical grade products for both muscle strengthening and pain relief. Bio-Medical Research Ltd. complies with 21 CFR 820 and is registered to I.S. EN ISO 13485:2003, Medical Device Quality Management System for the design, manufacture and distribution of electro-medical devices.

Kneehab XP, Type 412/421 device complies with the following international safety standards:

- IEC 60601-1 (1998) + A1: 1991, A2: 1995, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2 (2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility Requirements & Tests.
- IEC 60601-2-10 (1987) + A1: 2001 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

A risk management plan has been carried out to I.S. EN ISO 14971 2007.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bio-Medical Research LTD.
c/o Anne Marie Keenan
Quality/Regulatory Engineer
Parkmore Business Park, West
Galway
Ireland EI

AUG - 3 2011

Re: K110350
Trade/Device Name: Kneehab XP, Type 412/421
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Codes: GZJ, IPF, NYN
Dated: June 24, 2011
Received: June 30, 2011

Dear Ms. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Keoia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110350

Device Name: Kneehab XP, Type 412/421

Indications for Use:

The Kneehab XP, Type 412/421, Indications for use are as follows:

In NMES mode (Programs 1-6) the Kneehab XP is intended to:

- Maintain or increase the range of motion.
- Prevention or retardation of disuse atrophy
- Re-educate muscles
- Early post-surgical quadriceps strengthening and improved post surgical knee stability secondary to quadriceps strengthening
- Relax muscle spasms
- Increase blood circulation

In TENS Mode (Programs 7 - 9) the Kneehab XP is intended to:

- Provide symptomatic relief and management of chronic, intractable pain
- Provide an adjunctive treatment in the management of acute, post-surgical or post-traumatic pain
- Provide symptomatic relief and management of intractable pain and relief of pain associated with arthritis
- Provide an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110350